DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 17, 2015

MX Orthopedics, Corporation
Mr. Howard L. Schrayer
Regulatory Affairs Consultant
12 Suburban Park Drive
Billerica, Massachusetts 01821

Re: K143622
Trade/Device Name: dynaMX™ Compression Staple
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR
Dated: May 8, 2015
Received: May 11, 2015

Dear Mr. Schrayer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143622

Device Name
dynaMX Compression Staple

Indications for Use *(Describe)*

The dynaMX Compression Staple is indicated for:

Fracture and osteotomy fixation and joint arthrodesis of the hand and foot and,
Fixation of proximal tibial metaphysis osteotomy

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Per 21 CFR 807.92)

General Company Information

Name: MX Orthopedics, Corp.
Contact: Howard Schrayer
Regulatory Affairs Consultant

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Date Prepared June 12, 2015

General Device Information

Product Name: dynaMX™ Compression Staple

Classification: “Bone Fixation Staple”
Product code: JDR - Class II
21 CFR 888.3030

Predicate Device

BioMedical Enterprises	Speed™ Staple (Originally cleared as Osstaple™ Chill) [510(k) Number K102107]
BioMedical Enterprises	OSStaple™ Staple (Originally cleared as Memograph™) [510(k) K993714]

Description

The dynaMX Compression Staple provides a means of bone fixation in the management of fractures and reconstructive surgery.

- The dynaMX Compression Staples are made of biocompatible Nitinol. The legs of the staple are designed to exhibit superelastic properties at room temperature.
- Staples with a bridge length of 11mm and longer are designed with a bridge that can be bent to contour to the bone surface.

Indications for Use

The dynaMX™ Compression Staple is indicated for:

- Fracture and osteotomy fixation and joint arthrodesis of the hand and foot and,
- Fixation of proximal tibial metaphysis osteotomy

Substantial Equivalence

A series of laboratory studies (bench tests) have been conducted to verify the suitability of the dynaMX™ Compression Staple for its intended use, establish Substantial Equivalence with the predicate devices and confirm reproducibility of the packaging.

These tests include:

Elastic Static Bending Testing
Bending Fatigue Testing
Staple Pull-Out Force
Corrosion Testing
Package Seal Strength Verification

The biocompatibility of Nitinol has been well-established. A reference publication that describes the biocompatibility is also appended, together with a copy of the shelf-life / stability protocol.

This submission supports the position that the MX Orthopedics dynaMX™ Compression Staple is substantially equivalent to previously cleared devices, including those listed above. A number of predicate devices list the same range of clinical uses.

Conclusions

MX Orthopedics, Corp. believes that the information provided establishes that similar legally marketed devices have been used for the same clinical applications as the MX Orthopedics dynaMX™ Compression Staple. The materials from which the MX Orthopedics device is fabricated have an established history of use, and the devices have been tested in accordance with applicable FDA guidelines.